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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/664,225

09/16/2003

Pontus von Bahr

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EXAMINER

ALEXANDER, LYLE

ART UNIT

PAPER NUMBER

1743

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/664,225

Applicant(s)

VON BAHR ET AL.

Examiner

Lyle A. Alexander

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/26/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 6-15, 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is not clear where the flow regulator(6) is positioned in the device. The claim is worded such that it could be regulating the air as the patient exhales it. However, it would make more sense that the regulator is regulating the stored portion of the exhaled air.

Claim 6 is not clear what type of means is intended to verify the parameters and control exhalation.

Claim 10 is not clear what type of structure is intended by "maze".

Claim 14 and 18 describe smartcards, but fail to specify the smart cards comprise a computer readable medium.

Claim 15 is not clear how the device is adapted to users and different user groups based upon the smartcard. Clarification could be achieved by specifying the smartcard comprises a computer readable medium.

Claim 17 does not specify any structure to accomplish this function and appears to be a method of use which is of no patentable moment with respect to the pending apparatus claims.

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Claims 26 states the patient is entering information , but fails to describe where the information is being entered such that the appropriate information can be gleaned.

Claim 29 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The claims are directed to method but fail to put forth any method steps, fail to state what the parameters are and how the parameter are calculated .

Claim 29 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 11-12 and 17-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by EP 0904729 (referenced hereafter as EP).

Figure 1 shows the ventilator(2) connected to a patient(4). The expired gas is transferred via line(8) to the analysis unit(10). The gas is supplied to a mixing chamber(20) before sample measurement. Subsequently, the gas is

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carried through a first check valve(24) to a first reciprocating pump(30) where the gas is pressurized and when the desired pressure is obtained the gas goes past the second check valve(34) to a second reciprocating pump(36) that compresses the gas to a much smaller volume (e.g. a third or tenth as large) and has been read on the claimed *buffer chamber*. Regulator switch(40) controls the first and second gas lines. The combination of the check valves and switch has been read on the pressure regulators and pressure sensor respectively. Paragraph [0029] teaches use of a dehumidifier(44) which has been read on the claimed means to equalize the humidity. Paragraph[0031] teaches the analysis unit(52) is a traditional spectrophotometer and has been read on the claimed *NO sensor*. The gas lines taught after the pumps have been read on the claimed *buffer chamber consist of a length of tube*. Additionally, the claimed limitations specifying the flow of the gas and/or feedback to the patient, the Office maintains EP has the appropriate means to accomplish all of these functions.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10,22-23,25 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0904729 (referenced hereafter as EP).

See EP *supra*.

EP is silent to the claimed maze shape of the chamber, the specific type of audible feedback given to the patient and the claimed flow rates.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. Selection of audible feedback and the chosen rates of flow have well known and expected results and would be result effective variables.

It would have been within the skill of the art to modify EP and use audible feedback, a flow rate of 0.5-10 ml/s to the sensor and the flow rate up to the sensor lower than the exhalation flow rate as optimization of result effective variables.

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Claims 14-15, 18 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0904729 (referenced hereafter as EP) in view of Holowko et al.

See EP supra.

EP is silent to the use of the claimed "smartcard".

Holowko et al. a smartcard is desirable because it will store all of the patient's pertinent medical information and history. This is advantageous because many patients may not accurately remember their medical history or may be impaired and unable to communicate. Holowko et al. further teach current information can be continually added to the smartcard.

It would have been within the skill of the art to modify EP in view of Holowko et al. and use a smartcard to contain specific patient information to gain the above advantages.

Claims 16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0904729 (referenced hereafter as EP) in view of Oswin et al.

See EP supra.

EP teaches use of a convention spectrophotometry to determine the NO and is silent to the claimed electrochemical cell.

Oswin et al. teach measurements of breath oxides using an electrochemical cell. The abstract teaches electrochemical cells are advantageous because they do not require additional heat input.

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It would have been within the skill of the art to modify EP in view of Oswin et al. and use an electrochemical cell to gain the above advantages.

Claims 13 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0904729 (referenced hereafter as EP) in view of Birks et al. (USP 7,045,359).

See EP supra.

EP is silent to the use of NO scrubber.

Birks et al. use a NO scrubber on a sample prior to the analyzer to aid in the NO calculations and calibrations.

It would have been within the skill of the art to modify EP in view of Birks et al. and use a NO scrubber on the breath sample prior to analysis to gain the above advantages.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander
Primary Examiner
Art Unit 1743

